General

Guideline Title

Chemotherapy and targeted therapy for women with human epidermal growth factor receptor 2–negative (or unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline.

Bibliographic Source(s)

Partridge AH, Rumble RB, Carey LA, Come SE, Davidson NE, Di Leo A, Gralow J, Hortobagyi GN, Moy B, Yee D, Brundage SB, Danso MA, Wilcox M, Smith IE. Chemotherapy and targeted therapy for women with human epidermal growth factor receptor 2-negative (or unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2014 Oct 10;32(29):3307-29. [96 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the rating of evidence (High, Intermediate, Low, Insufficient); types of recommendations (Evidence-Based, Formal Consensus, Informal Consensus, No Recommendation); and strength of recommendations (Strong, Moderate, Weak) are provided at the end of the "Major Recommendations" field.

1. Endocrine therapy, rather than chemotherapy, should be offered as the standard first-line treatment for patients with hormone receptor–positive advanced/metastatic breast cancer, except for immediately life threatening disease or if there is concern regarding endocrine resistance.
    A. The main benefit is less toxicity and better quality of life for the patient associated with endocrine therapy compared with chemotherapy (potential benefit: high). The harm is that metastatic disease could progress rapidly and prove fatal if there is no response, but the risk of this is low (potential harm: low).
    B. The quality of the evidence is intermediate, and is based on the National Collaborating Centre for Cancer (NCCC) systematic review.
    C. The strength of this recommendation is strong and is supported by the evidence and expert consensus.

- *Qualifying statement: It should be noted that the basis for this recommendation is the relative likelihood of response to chemotherapy versus endocrine therapy and not the rapidity of response, for which there are no good data.*

2. Sequential single-agent chemotherapy rather than combination therapy should be offered, although combination regimens may be considered

for immediately life-threatening disease for which time may allow only one potential chance for therapy.

   A. The benefit is less toxicity and better quality of life (potential benefit: high). The potential harm is for rapidly progressing, life-threatening disease to escape control if response to a single agent isn't achieved (potential harm: high). The main benefit is there is less toxicity and better quality of life for the patient associated with sequential single agent chemotherapy compared with combination chemotherapy (potential benefit: high). The harm is that metastatic disease could progress rapidly if there is no response, but the risk of this is low (potential harm: low).
   B. The evidence quality is high, and includes a large randomized controlled trial (RCT).
   C. The strength of this recommendation is strong.

3. With regard to targeted agents, the role of bevacizumab is controversial, and this therapy should be considered (where available) with single-agent chemotherapy only when there is immediately life-threatening disease or severe symptoms, in view of improved response rates (similar to Recommendation 2 regarding the use of combination chemotherapy). It is recognized that there is not currently an approved indication for bevacizumab in the United States because the weight of evidence shows no significant survival benefit. Other targeted agents should not be used either in addition to, or as a replacement for, chemotherapy in this setting outside of a trial.
   A. The benefit is improved disease control (potential benefit: moderate). The potential harms are unique toxicity, increased costs, and barriers to access (potential harm: high).
   B. The quality of the evidence is high and is supported by multiple trials.
   C. The strength of the recommendation is moderate and is based on both evidence and expert consensus.

- *Qualifying statement: Bevacizumab added to single-agent chemotherapy improves response and progression-free survival but not overall survival.*

4. No single agent has demonstrated superiority in the treatment of patients with advanced breast cancer, and there are several active agents appropriate for first-line chemotherapy. The evidence for efficacy is strongest for taxanes and anthracyclines. Other options include capecitabine, gemcitabine, platinum-based compounds, vinorelbine, and ixabepilone. Treatment selection should be based on previous therapy, differential toxicity, comorbid conditions, and patient preferences. Specifically, drugs for which clinical resistance has already been shown should not be reused.
   A. The benefit is a patient-tailored approach with potential improvements in disease control and quality of life (potential benefit: high). The harm is the potential use of a less active agent (potential harm: low).
   B. The evidence quality supporting the activity of a number of single agents is high, but there is insufficient evidence to support superiority of any single agent.
   C. The strength of the recommendation is strong and is based on the available evidence and expert consensus.
5. Chemotherapy should be continued until progression of disease as tolerated because it modestly improves overall survival and substantially improves progression-free survival, but this has to be balanced against toxicity and quality of life. Short breaks, flexibility in scheduling, or a switch to endocrine therapy (in patients with hormone receptor–positive disease) may be offered to selected patients.
   A. The benefits are more time before disease-progression and modestly improved survival (potential benefit: high). The harm is more prolonged toxicity (potential harm: moderate).
   B. The evidence quality is high, and is based on a systematic review with meta-analysis.
   C. The strength of the recommendation is strong, and is supported by evidence and expert consensus.

- *Qualifying statement: It is recognized that the balance between continuing treatment to maintain disease control and coping with progressive adverse events (AEs) and/or toxicity is a difficult one. It will be influenced by many factors, including drug used (e.g., long-term use of capecitabine is relatively easy, whereas docetaxel is severely limited by cumulative toxicity) and requires a continuing dialogue between doctor and patient.*

6. Chemotherapy regimens should not be specifically tailored to different breast cancer subtypes (e.g., triple negative, lobular) at the present time due to the absence of evidence proving differential efficacies. In addition, in vitro chemoresistance assays should not be used to select treatment.
   A. The benefits are not omitting potentially efficacious treatment and cost-saving on in vitro assays (potential benefit: high).
   B. Current evidence shows no convincing basis for either of these approaches.
   C. The strength of this recommendation is moderate, and is supported by expert consensus.

- *Qualifying statement: This recommendation will need to be modified if ongoing or future research addressing this important issue suggests benefits of tailoring.*

7. Second- and later-line therapy may be of clinical benefit and should be offered as determined by previous treatments, toxicity, coexisting medical conditions, and patient choice. As with first-line treatment, no clear evidence exists for the superiority of one specific drug or

regimen. Active agents include those active in first-line treatment.

A. The benefit is further chance of disease control and symptomatic improvement (potential benefit: high). The harm is toxicity (potential harm: high).
B. The quality of the evidence ranges from high to low as reported in multiple randomized trials.
C. The strength of the recommendation is strong and is based on expert consensus.

- *Qualifying statement: The most convincing data are for eribulin based on survival superiority against best standard treatment in a recent large RCT, but there is a lack of good comparative data between these various agents.*

8. Palliative care should be offered throughout the continuum of care. As there are diminishing returns with later lines of chemotherapy, clinicians should also offer best supportive care without further chemotherapy as an option.
   A. The benefits include a patient-centered approach emphasizing quality of life (potential benefit: high). The main harm is fear of abandonment and giving up hope, which can be addressed by effective communication and appropriate end-of-life planning (potential harm: moderate).
   B. The quality of the evidence is intermediate and is supported by several RCTs in patients with advanced cancer.
   C. The strength of the recommendation is strong and is supported by evidence, expert consensus, and another independent expert consensus.

- *Qualifying statement: Evidence suggests that response to second and subsequent lines of chemotherapy is strongly influenced by response to earlier treatment; patients whose disease has failed to respond to up to two initial lines of treatment are less likely to respond to a third or subsequent line.*

9. As there is no cure yet for patients with advanced breast cancer, clinicians should encourage all eligible patients to enroll onto clinical trials. This should include the option of phase II and even targeted phase I trials before all standard lines of therapy have been used, in the absence of immediately life-threatening disease.
   A. The benefits are more patients will be directed to clinical studies providing treatment benefits to them, and the medical community will benefit from more research to improve treatments available and on which to base treatment decisions. The potential harm is patients will receive inferior treatment.
   B. There is no strong evidence to suggest this approach might impair outcome.
   C. The strength of this recommendation is strong and based on expert consensus.

Definitions:

Guide for Rating Strength of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect however it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Guide for Types of Recommendations

Type of Recommendation	Definition
Evidence based	There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.
Formal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the Expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong,"

Type of Recommendation	Definition
	"moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in the Data Supplement (see the "Availability of Companion Documents" field).
Informal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

Guide for Strength of Recommendations

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Human epidermal growth factor receptor 2 (HER2)–negative (or unknown) advanced breast cancer

Guideline Category

Management

Risk Assessment

Treatment

Clinical Specialty

Oncology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Social Workers

Guideline Objective(s)

To identify optimal chemo- and targeted therapy for women with human epidermal growth factor 2 (HER2)– negative (or unknown) advanced breast cancer

Target Population

Women with human epidermal growth factor 2 (HER2)-negative (or unknown) advanced breast cancer

Interventions and Practices Considered

1. Endocrine therapy
2. Sequential single-agent chemotherapy
    - Based on previous therapy, differential toxicity, comorbid conditions, and patient preferences
    - Continued until progression of disease as tolerated
3. Combination chemotherapy (for immediate life-threatening disease only)
4. Targeted agents (bevacizumab with single-agent chemotherapy)
5. Second- and later-line therapies
6. Palliative care
7. Enrollment in clinical trials

Major Outcomes Considered

- Survival
- Progression-free survival
- Response
- Quality of life
- Adverse effects

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Review

American Society of Clinical Oncology (ASCO) guidelines are based on systematic reviews of the literature. A protocol for each systematic review defines parameters for a targeted literature search. Additional parameters include relevant study designs, literature sources, types of reports, and prespecified inclusion and exclusion criteria for literature identified. The protocol for this guideline was reviewed and approved by the ASCO Clinical Practice Guidelines Committee's Breast Cancer Guideline Advisory Group (GAG).

Literature Search Strategy

For this clinical practice guideline (CPG), the recommendations were developed by an Expert Panel with multidisciplinary representation using a systematic review (January 2009 through to May 2013 for first-line trials; January 1993 through to May 2013 for second-line trials) of systematic reviews with or without meta-analysis, meta-analyses, randomized clinical trials (RCTs), and clinical experience.

Study Selection Criteria

Articles were selected for inclusion in the systematic review of the evidence on the basis of the following criteria:

- Included women 18 years of age and older with human epidermal receptor 2 (HER2)-negative (or unknown) advanced breast cancer
- Were fully published reports identified using the MEDLINE (OVID) database or abstracts from specific conference proceedings (San Antonio Breast Cancer Symposium; 2011, 2012) and ASCO abstracts (2012, 2013)
- Included a minimum of 25 patients per study arm
- Were published in English

Number of Source Documents

A total of 78 studies met the eligibility criteria and form the evidentiary basis for the guideline recommendations, comprising 20 systematic reviews and/or meta-analyses (see Table 1 in the original guideline document), 30 studies reporting on first-line treatment options, and 28 reporting on second line or greater treatment options (see Table 2 in the original guideline document). Two of the included studies reported on both first- and second-line treatment and are included in both sections.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Guide for Rating Strength of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect however it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Search results were reviewed by the Practice Guidelines Specialist and papers deemed eligible for full text review were obtained and data were extracted. These data were also reviewed by the lead authors and audited by an American Society of Clinical Oncology (ASCO) staff member. Disagreements were resolved through discussion and consultation with the lead authors if necessary.

Study Quality

Study quality was formally assessed for all 30 of the included first-line trials and for all 28 of the included second-line trials, with details available in the Data Supplement (see the "Availability of Companion Documents" field). Design aspects related to the individual study quality were assessed by one reviewer and included factors such as blinding, allocation concealment, placebo control, intention to treat, funding sources, and so on. The risk of bias was assessed as low, intermediate, or high for most of the identified evidence. It was determined that this body of evidence represented trials of acceptable quality, and no exclusions were made on the basis of the assessment.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition

The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee convened an Expert Panel with multidisciplinary representation in medical oncology, community oncology, patient representation, and guideline methodology. The Expert Panel members are listed in the Appendix in the original guideline document.

Guideline Development Process

The Expert Panel, who met via teleconference and corresponded through email, were asked to contribute to the development of the guideline, provide critical review, interpret evidence, and finalize the guideline recommendations in consideration of the evidence. Members of the Expert Panel are responsible for drafting the penultimate version of guideline, which was then circulated for external review and submitted to the *Journal of Clinical Oncology (JCO)* for editorial review and publication.

Development of Recommendations

The recommendations were developed on the basis of systematic reviews of the scientific literature and expert panel consensus, using the best available evidence and clinical experience as guides. The recommendations are evidence based and informed by randomized controlled trial (RCT) data. Summary descriptions of results are provided in the literature review and analysis section of the original guideline document. Ratings for the type of recommendation and strength of the evidence are offered (see the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields).

The guideline recommendations were crafted, in part, by using the Guidelines Into Decision Support (GLIDES) methodology and accompanying BRIDGE-Wiz software (see the Methodology Supplement [see the "Availability of Companion Documents" field]). A guideline implementability review was conducted to improve clarity around recommended actions for clinical practice.

Rating Scheme for the Strength of the Recommendations

Guide for Types of Recommendations

Type of Recommendation	Definition

Type of Recommendation	Definition
Evidence based	There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.
Formal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the Expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in the Data Supplement (see the "Availability of Companion Documents" field).
Informal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

Guide for Strength of Recommendations

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Members of the Expert Panel are responsible for drafting the penultimate version of the guideline, which is then circulated for external review and submitted to the *Journal of Clinical Oncology (JCO)* for editorial review and publication.

The draft clinical practice guideline (CPG) was distributed to three clinicians who were not members of the Expert Panel for review (see the Acknowledgments section of the original guideline document). Main comments included: inclusion of several trials that were outside of the search dates for the systematic review, lack of availability of the targeted therapy agent in some areas, a request to change the language around the likelihood of finding an optimal therapy regimen that would address the needs of all patients, and other changes of an editorial nature. All comments were considered by the Working Group, and changes were made to address all the main comments.

All American Society of Clinical Oncology (ASCO) guidelines are reviewed and approved by the ASCO Clinical Practice Guideline Committee before publication. This guideline was approved by the ASCO Clinical Practice Guideline Committee on January 31, 2014.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate treatment of women with human epidermal growth factor receptor 2 (HER2)-negative (or unknown) advanced breast cancer
- Refer to the "Major Recommendations" field for information concerning benefits vs. harms for each recommendation.

Potential Harms

- There are many agents available for the systemic treatment of breast cancer that may result in tumor response or stability; however, most antineoplastic agents are also associated with adverse events (AEs) that may impair quality of life (QoL) and even cause life-threatening toxicity.
- In one study there were no significant differences between the duration of overall survival (OS) between single-agent and combination arms, and the combination arm was associated with more severe adverse effects. Another pivotal trial reported as well, along with two follow-up articles, that single-agent sequential therapy is likely no different from combination regimens, although combination regimens are associated with greater, and more severe, AEs.
- Table 4 in the original guideline document reports on the acute and chronic adverse effects of various regimens.
- Refer to the "Major Recommendations" field for information concerning benefits vs. harms for each recommendation.

Qualifying Statements

Qualifying Statements

- The Clinical Practice Guidelines and other guidance published herein are provided by the American Society of Clinical Oncology, Inc. (ASCO) to assist providers in clinical decision making. The information herein should not be relied on as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Further, the information is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. Recommendations reflect high, moderate, or low confidence that the recommendation reflects the net effect of a given course of action. The use of words like "must," "must not," "should," and "should not" indicates that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an "as is" basis and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information, or for any errors or omissions.
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the National Cancer Institute, National Institutes of Health, the Food and Drug Administration, or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

Guideline Implementation

American Society of Clinical Oncology (ASCO) guidelines are developed for implementation across health settings. Barriers to implementation include the need to increase awareness of the guideline recommendations among front-line practitioners and cancer survivors, and to provide adequate services in the face of limited resources. The guideline Bottom Line was designed to facilitate implementation of recommendations. This guideline will be distributed widely through the ASCO Practice Guideline Implementation Network. ASCO guidelines are posted on the ASCO Web site and most often published in *Journal of Clinical Oncology* and *Journal of Oncology Practice*.

For additional information on the American Society for Clinical Oncology (ASCO) implementation strategy, please see the ASCO Web site.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Partridge AH, Rumble RB, Carey LA, Come SE, Davidson NE, Di Leo A, Gralow J, Hortobagyi GN, Moy B, Yee D, Brundage SB, Danso MA, Wilcox M, Smith IE. Chemotherapy and targeted therapy for women with human epidermal growth factor receptor 2-negative (or

unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2014 Oct 10;32(29):3307-29. [96 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Oct 10

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology

Guideline Committee

Expert Panel

Composition of Group That Authored the Guideline

Expert Panel Members: Ann H. Partridge, MD (*Co-chair*), Dana-Farber Cancer Institute, Boston, MA; Ian E. Smith, MD (*Co-chair*), Royal Marsden Hospital, London, UK; Shelley B. Brundage; Lisa A. Carey, MD, University of North Carolina, Chapel Hill, NC; Steven E. Come, MD, Beth Israel Deaconess Medical Center, Boston, MA; Michael A. Danso, MD, Virginia Oncology Associates, Norfolk, VA; Nancy E. Davidson, MD, University of Pittsburgh Cancer Institute/University of Pittsburgh Medical Center, Pittsburgh, PA; Angelo Di Leo, MD, Sandro Pitigliani Medical Oncology Unit, Prato, Italy; Julie Gralow, MD, University of Washington/Seattle Cancer Care Alliance, Seattle, WA; Gabriel N. Hortobagyi, MD, University of Texas, MD Anderson Cancer Center, Houston, TX; Beverly Moy, MD, Massachusetts General Hospital, Boston, MA; R. Bryan Rumble, MSc, American Society of Clinical Oncology, Alexandria, VA; Maggie Wilcox; Douglas Yee, MD, University of Minnesota/Masonic Cancer Center, Minneapolis, MN

Financial Disclosures/Conflicts of Interest

The Expert Panel was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflict of Interest Management Procedures for Clinical Practice Guidelines (Procedures; summarized at http://www.asco.org/guidelinescoi). Members of the Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests that are relevant to the subject matter of the guideline, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as the result of promulgation of the guideline. Categories for disclosure include employment relationships, consulting arrangements, stock ownership, honoraria, research funding, and expert testimony. In accordance with the Procedures, the majority of the members of the Panel did not disclose any such relationships.

Authors' Disclosures of Potential Conflicts of Interest

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

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No relationship to disclose

R. Bryan Rumble
No relationship to disclose

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Consulting or Advisory Role: AstraZeneca, Blue Cross and Blue Shield of North Carolina Board of Trustees, G1 Therapeutics Genentech GlaxoSmithKline Novartis
Research Funding: Genentech GlaxoSmithKline Sanofi

Steven Come
Consulting or Advisory Role: Genentech/Roche
Expert Testimony: Pfizer

Nancy Davidson
No relationship to disclose

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Travel, Accommodations, Expenses: Roche Novartis Pfizer AstraZeneca Eisai

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No relationship to disclose

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No relationship to disclose

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site .

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; E-mail: guidelines@asco.org.

Availability of Companion Documents

The following are available:

- Clinical practice guideline 1-17: chemo- and targeted therapy for women with HER2-negative (or unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline. Methodology supplement. Alexandria (VA): American Society of Clinical Oncology; 2014. 8 p. Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site .
- Clinical practice guideline 1-17: chemo- and targeted therapy for women with HER2 negative (or unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline. Data supplement. Alexandria (VA): American Society of Clinical Oncology; 2014. 40 p. Electronic copies: Available from the ASCO Web site .
- Chemo- and targeted therapy for women with HER2 negative (or unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2014. Electronic copies: Available in PDF and PowerPoint from the ASCO Web site .
- Chemo- and targeted therapy for women with HER2 negative (or unknown) advanced breast cancer: American Society of Clinical Oncology clinical practice guideline. Summary of recommendations. Alexandria (VA): American Society of Clinical Oncology; 2014. 7 p. Electronic copies: Available from the ASCO Web site .

Patient Resources

The following is available:

- Treatment of advanced HER2-negative breast cancer. Patient information. 2014. Electronic copies: Available from the Cancer.Net Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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